

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE HOME HEALTH
AGENCY PROVIDER
COMPLIANCE AUDIT:
MERCY HEALTH VISITING
NURSE SERVICES**

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Office of Inspector General

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The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

Report in Brief

Date: September 2020

Report No. A-05-18-00035

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL



Why **OIG** Did This Audit

Under the Medicare home health prospective payment system (PPS), the Centers for Medicare & Medicaid Services pays home health agencies (HHAs) a standardized payment for each 60-day episode of care that a beneficiary receives. The PPS payment covers intermittent skilled nursing and home health aide visits, therapy (physical, occupational, and speech-language pathology), medical social services, and medical supplies.

Our prior audits of home health services identified significant overpayments to HHAs. These overpayments were largely the result of HHAs improperly billing for services to beneficiaries who were not confined to the home (homebound) or were not in need of skilled services.

Our objective was to determine whether Mercy Health Visiting Nurse Services (Mercy) complied with Medicare requirements for billing home health services on selected types of claims.

How **OIG** Did This Audit

We selected a simple random sample of 100 home health claims and submitted these claims to medical review.

Medicare Home Health Agency Provider Compliance Audit: Mercy Health Visiting Nurse Services

What **OIG** Found

Mercy did not comply with Medicare billing requirements for 23 of the 100 home health claims that we reviewed. For these claims, Mercy received overpayments of \$42,466 for services provided in calendar years (CYs) 2016 and 2017. Specifically, Mercy incorrectly billed Medicare for (1) services provided to beneficiaries who were not homebound or (2) services provided to beneficiaries who did not require skilled services. On the basis of our sample results, we estimated that Mercy received overpayments of approximately \$1.1 million for CYs 2016 and 2017.

What **OIG** Recommends and Mercy Comments

We made several recommendations to Mercy, including that it (1) refund to the Medicare program the portion of the estimated \$1.1 million in overpayments for claims incorrectly billed that are within the reopening period; (2) exercise reasonable diligence to identify and return overpayments, in accordance with the 60-day rule, for claims that are outside the reopening period; and (3) exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit period. We also made several procedural recommendations.

In written comments on our draft report, Mercy generally disagreed with our findings and one of our recommendations and partially agreed with two recommendations. After reviewing Mercy's response and further considering our medical review results, we maintain that our findings and recommendations are valid.

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INTRODUCTION

WHY WE DID THIS AUDIT

For calendar year (CY) 2016, Medicare paid home health agencies (HHAs) about \$18 billion for home health services. The Centers for Medicare & Medicaid Services (CMS) determined through its Comprehensive Error Rate Testing (CERT) program that the 2016 improper payment error rate for home health claims was 42 percent, or about \$7.7 billion. Although Medicare spending for home health care accounts for only about 5 percent of fee-for-service spending, improper payments to HHAs account for more than 18 percent of the total 2016 fee-for-service improper payments (\$41 billion). This audit is part of a series of audits of HHAs. Using computer matching, data mining, and data analysis techniques, we identified HHAs at risk for noncompliance with Medicare billing requirements. Mercy Health Visiting Nurse Services (Mercy) was one of those HHAs.

OBJECTIVE

Our objective was to determine whether Mercy complied with Medicare requirements for billing home health services on selected types of claims.

BACKGROUND

The Medicare Program and Payments for Home Health Services

Medicare Parts A and B cover eligible home health services under a prospective payment system (PPS). The PPS covers part-time or intermittent skilled nursing care and home health aide visits, therapy (physical, occupational, and speech-language pathology), medical social services, and medical supplies. Under the home health PPS, CMS pays HHAs for each 60-day episode of care that a beneficiary receives.

CMS adjusts the 60-day episode payments using a case-mix methodology based on data elements from the Outcome and Assessment Information Set (OASIS). The OASIS is a standard set of data elements that HHA clinicians use to assess the clinical severity, functional status, and service utilization of a beneficiary receiving home health services. CMS uses OASIS data to assign beneficiaries to the appropriate categories, called case-mix groups, to monitor the effects of treatment on patient care and outcomes and to determine whether adjustments to the case-mix groups are warranted. The OASIS classifies HHA beneficiaries into 153 case-mix groups that are used as the basis for the Health Insurance Prospective Payment System (HIPPS)

payment codes¹ and represent specific sets of patient characteristics.² CMS requires HHAs to submit OASIS data as a condition of payment.³

CMS administers the Medicare program and contracts with four of its Medicare administrative contractors to process and pay claims submitted by HHAs.

Home Health Agency Claims at Risk for Incorrect Billing

In prior years, our audits at other HHAs identified findings in the following areas:

- beneficiaries did not always meet the definition of “confined to the home,”
- beneficiaries were not always in need of skilled services,
- HHAs did not always submit OASIS data in a timely fashion, and
- services were not always adequately documented.

For the purposes of this report, we refer to these areas of incorrect billing as “risk areas.”

Medicare Requirements for Home Health Agency Claims and Payments

Medicare payments may not be made for items and services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member” (Social Security Act (the Act) § 1862(a)(1)(A)). Sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act and regulations at 42 CFR § 409.42 require, as a condition of payment for home health services, that a physician certify and recertify that the Medicare beneficiary is:

- confined to the home (homebound);
- in need of skilled nursing care on an intermittent basis or physical therapy or speech-language pathology, or has a continuing need for occupational therapy;
- under the care of a physician; and

¹ HIPPS rate codes represent specific sets of patient characteristics (or case-mix groups) on which payment determinations are made under several Medicare prospective payment systems, including those for skilled nursing facilities, inpatient rehabilitation facilities, and HHAs.

² The final payment is determined at the conclusion of the episode of care using the OASIS information but also factoring in the number and type of home health services provided during the episode of care.

³ 42 CFR §§ 484.20, 484.55, 484.210(e), and 484.250(a)(1); 74 Fed. Reg. 58077, 58110-58111 (Nov. 10, 2009); and CMS’s *Medicare Program Integrity Manual*, Pub. No. 100-08, chapter 3, § 3.2.3.1.

- receiving services under a plan of care that has been established and periodically reviewed by a physician.

Furthermore, as a condition for payment, a physician must certify that a face-to-face encounter occurred no more than 90 days prior to the home health start-of-care date or within 30 days of the start of care (42 CFR § 424.22(a)(1)(v)). In addition, the Act precludes payment to any provider of services or other person without information necessary to determine the amount due the provider (§ 1833(e)).

The determination of “whether care is reasonable and necessary is based on information reflected in the home health plan of care, the OASIS as required by 42 CFR § 484.55, or a medical record of the individual patient” (*Medicare Benefit Policy Manual* (the Manual), chapter 7, § 20.1.2). Coverage determination is not made solely on the basis of general inferences about patients with similar diagnoses or on data related to utilization generally but is based upon objective clinical evidence regarding the beneficiary’s individual need for care (42 CFR § 409.44(a)).

The Office of Inspector General (OIG) believes that this audit report constitutes credible information of potential overpayments. Upon receiving credible information of potential overpayments, providers must exercise reasonable diligence to identify overpayments (i.e., determine receipt of and quantify any overpayments) during a 6-year lookback period. Providers must report and return any identified overpayments by the later of (1) 60 days after identifying those overpayments or (2) the date that any corresponding cost report is due (if applicable). This is known as the 60-day rule.⁴

The 6-year lookback period is not limited by OIG’s audit period or restrictions on the Government’s ability to reopen claims or cost reports. To report and return overpayments under the 60-day rule, providers may request the reopening of initial claims determinations, submit amended cost reports, or use any other appropriate reporting process.⁵

Appendix B contains the details of selected Medicare coverage and payment requirements for HHAs.

Mercy Health Visiting Nurse Services

Mercy is a not-for-profit HHA located in Muskegon, Michigan. National Government Services, LLC, its Medicare administrative contractor, paid Mercy approximately \$12 million for 4,972 claims for services provided in CYs 2016 and 2017 (audit period) according to CMS’s National Claims History (NCH) data.

⁴The Act § 1128J(d); 42 CFR §§ 401.301–401.305; and 81 Fed. Reg. 7654 (Feb. 12, 2016).

⁵42 CFR §§ 401.305(d), 405.980(c)(4), and 413.24(f); CMS, *Provider Reimbursement Manual*, Pub. No. 15-1, part 1, § 2931.2; 81 Fed. Reg. at 7670.

HOW WE CONDUCTED THIS AUDIT

Our audit covered \$10,723,568 in Medicare payments to Mercy for 3,894 claims.⁶ These claims were for home health services provided in CYs 2016 and 2017.⁷ We selected a simple random sample of 100 claims with payments totaling \$284,285 for audit. We evaluated compliance with selected billing requirements and submitted these claims to an independent medical review contractor to determine whether the services met coverage, medical necessity, and coding requirements.

We conducted this performance audit in accordance with generally accepted government auditing standards (GAGAS). Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A contains the details of our audit scope and methodology, Appendix C contains our statistical sampling methodology, Appendix D contains our sample results and estimates, and Appendix E contains the types of errors for each sample item.

FINDINGS

Mercy did not comply with Medicare billing requirements for 23 of the 100 home health claims that we reviewed. For these claims, Mercy received net overpayments of \$42,466 for services provided in CYs 2016 and 2017. Specifically, Mercy incorrectly billed Medicare for:

- services provided to beneficiaries who were not homebound and
- services provided to beneficiaries who did not require skilled services.

These errors occurred primarily because Mercy did not have adequate controls to prevent the incorrect billing of Medicare claims within selected risk areas. On the basis of our sample results, we estimated that Mercy received overpayments of at least \$1,074,136 for the audit period.⁸ As of the publication of this report, this amount included claims outside of the 4-year claim reopening period.

⁶ In developing this sampling frame, we excluded from our audit home health claim payments for low utilization payment adjustments, partial episode payments, and requests for anticipated payments.

⁷ CYs were determined by the HHA claim “through” date of service. The through date is the last day on the billing statement covering services provided to the beneficiary.

⁸ To be conservative, we recommend recovery of overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

MERCY HEALTH VISITING NURSE SERVICES' BILLING ERRORS

Mercy incorrectly billed Medicare for 23 of the 100 sampled claims, which resulted in net overpayments of \$42,466.

Beneficiaries Were Not Homebound

Federal Requirements for Home Health Services

For the reimbursement of home health services, the beneficiary must be “confined to the home” (the Act §§ 1814(a)(2)(C) and 1835(a)(2)(A) and Federal regulations (42 CFR § 409.42)). According to section 1814(a) of the Act:

[A]n individual shall be considered to be “confined to his home” if the individual has a condition, due to illness or injury, that restricts the ability of the individual to leave his or her home except with the assistance of another individual or the aid of a supportive device (such as crutches, a cane, a wheelchair, or a walker), or if the individual has a condition such that leaving his or her home is medically contraindicated. While an individual does not have to be bedridden to be considered “confined to his home,” the condition of the individual should be such that there exists a normal inability to leave home and that leaving home requires a considerable and taxing effort by the individual.

CMS provided further guidance and specific examples in the Manual (chapter 7, § 30.1.1). Revision 208 of § 30.1.1 (effective January 1, 2015) and Revision 233 of § 30.1.1 (effective January 1, 2017) covered different parts of our audit period.⁹ The Manual states that for a patient to be eligible to receive covered home health services under both Parts A and B, the law requires that a physician certify in all cases that the patient is confined to his or her home and that an individual will be considered “confined to the home” (homebound) if the following two criteria are met:

Criteria One

The patient must either:

- because of illness or injury, need the aid of supportive devices, such as crutches, canes, wheelchairs, and walkers; the use of special transportation; or the assistance of another person in order to leave his or her place of residence; or

⁹ Coverage guidance is substantively identical in both versions of § 30.1.1 in effect during our audit period. The only difference is Revision 233, effective January 1, 2017, provides further clarification of existing policies for clinicians who must decide whether to certify that a patient is homebound.

- have a condition such that leaving his or her home is medically contraindicated.

If the patient meets one of the Criteria One conditions, then the patient must also meet two additional requirements defined in Criteria Two below.

Criteria Two

There must exist a normal inability to leave home, and leaving home must require a considerable and taxing effort.

Mercy Did Not Always Meet Federal Requirements for Home Health Services

For 16 of the sampled claims, Mercy incorrectly billed Medicare for home health episodes for beneficiaries who did not meet the above requirements for being homebound for the full episode (11 claims) or for a portion of one (5 claims).¹⁰

Example 1: Beneficiary Not Homebound – Entire Episode

The beneficiary's medical information did not support that the patient was homebound at the start of care. One day before the start of care, the patient went up and down stairs with minimal assistance, and the patient's medical progress notes encouraged frequent, short bouts of ambulation. He was encouraged to perform a home exercise plan with and without physical therapy. The day after the start of care, he ambulated 500 feet with a walker. The documentation stated that leaving the home would be a taxing effort; however, the documentation indicating the patient's physical function was not consistent with this. The patient's spouse noted during the episode of care that the patient was doing well and getting up and around frequently. The patient used an assistive device to leave the home, but the documentation did not reveal that the patient was homebound at the start of care. Leaving the home was not medically contraindicated and would not have required a considerable and taxing effort at the start of care.

Example 2: Beneficiary Not Homebound – Partial Episode

For another beneficiary, records showed a medical history including multiple malignant neoplasms, hypertension, and nicotine dependence. Home health services were ordered for home exercise program implementation to improve the patient's gait and balance. She required assistance with basic activities of daily living and was limited to ambulating 75 feet. Leaving the home would have

¹⁰Of these 16 claims with homebound errors, 9 claims were also billed with skilled services that were not medically necessary. Appendix E provides detail on the extent of the errors, if any, per claim reviewed.

required a considerable and taxing effort at the start of care. However, during the episode of care, the patient became independent with her home exercise program. She was able to ambulate more than 300 feet independently without an assistive device both inside and outside. There were no contraindications to leaving the home. The medical information does not support that she remained homebound throughout the entire episode of care.

These errors occurred because Mercy did not have sufficient controls in place.

Beneficiaries Did Not Require Skilled Services

Federal Requirements for Skilled Services

A Medicare beneficiary must need skilled nursing care intermittently, or physical therapy or speech-language pathology, or have a continuing need for occupational therapy (the Act §§ 1814(a)(2)(C) and 1835(a)(2)(A) and Federal regulations (42 CFR § 409.42(c))). In addition, skilled nursing services must require the skills of a registered nurse or a licensed practical nurse under the supervision of a registered nurse, must be reasonable and necessary to the treatment of the patient's illness or injury, and must be intermittent (42 CFR § 409.44(b) and the Manual, chapter 7, § 40.1).¹¹ Skilled therapy services must be reasonable and necessary to the treatment of the patient's illness or injury or to the restoration or maintenance of function affected by the patient's illness or injury within the context of the patient's unique medical condition (42 CFR § 409.44(c) and the Manual, chapter 7, § 40.2.1). Coverage of skilled nursing care or therapy does not turn on the presence or absence of a patient's potential for improvement but rather on the patient's need for skilled care. Skilled care may be necessary to improve a patient's current condition, to maintain the patient's current condition, or to prevent or slow further deterioration of the patient's condition (the Manual, chapter 7, § 20.1.2).

Mercy Did Not Always Meet Federal Requirements for Skilled Services

For 16 of the sampled claims, Mercy incorrectly billed Medicare for an entire episode (9 claims) or a portion of an episode (7 claims) for beneficiaries who did not meet the above Medicare requirements for coverage of skilled nursing or therapy services.¹²

¹¹ Skilled nursing services can include observation and assessment of a patient's condition, management and evaluation of a patient plan of care, teaching and training activities, and administration of medications, among other things (the Manual, chapter 7, § 40.1.2).

¹² Of the 16 claims for skilled services that were not medically necessary, 9 of the claims also contained errors related to the beneficiaries' homebound status. Appendix E provides detail on the extent of the errors, if any, per claim reviewed.

Example 3: Beneficiary Did Not Require Skilled Services – Partial Episode

A beneficiary in his first episode of care with a medical history including right hip osteoarthritis, right hip total arthroplasty, and vertigo was homebound. The beneficiary was to have skilled nursing for wound and cardiovascular status; however, the documentation does not reveal evidence of skilled nursing visits or wound or cardiovascular issues. Skilled nursing was not medically necessary during these dates. The patient required skilled physical therapy, but by his third visit, he met his physical therapy goals and used no assistive device. He demonstrated independence with a home exercise routine he was taught. Physical therapy was no longer medically necessary, and he no longer needed skilled home care.

These errors occurred because Mercy did not have sufficient controls in place.

OVERALL ESTIMATE OF OVERPAYMENTS

On the basis of our sample results, we estimated that Mercy received overpayments totaling at least \$1,074,136 for the audit period.

RECOMMENDATIONS

We recommend that Mercy Health Visiting Nurse Services:

- refund to the Medicare program the portion of the estimated \$1,074,136 in overpayments for claims incorrectly billed that are within the 4-year reopening period;¹³
- based on the results of this audit, exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule¹⁴ and identify any of those returned overpayments as having been made in accordance with this recommendation; and

¹³ OIG audit recommendations do not represent final determinations by Medicare. CMS, acting through a MAC or other contractor, will determine whether overpayments exist and will recoup any overpayments consistent with its policies and procedures. Providers have the right to appeal those determinations and should familiarize themselves with the rules pertaining to when overpayments must be returned or are subject to offset while an appeal is pending. The Medicare Part A and Part B appeals process has five levels (42 CFR § 405.904(a)(2)), and if a provider exercises its right to an appeal, the provider does not need to return overpayments until after the second level of appeal. Potential overpayments identified in OIG reports that are based on extrapolation may be re-estimated depending on CMS determinations and the outcome of appeals.

¹⁴ This recommendation does not apply to any overpayments that are both within our sampling frame (i.e., the population from which we selected our statistical sample) and refunded based upon the extrapolated overpayment amount. Those overpayments are already covered in the previous recommendation.

- strengthen its procedures to ensure that:
 - the homebound statuses of Medicare beneficiaries are verified and continually monitored and the specific factors qualifying beneficiaries as homebound are documented and
 - beneficiaries are receiving only reasonable and necessary skilled services.

**MERCY HEALTH VISITING NURSE SERVICES COMMENTS AND
OFFICE OF INSPECTOR GENERAL RESPONSE**

MERCY’S COMMENTS

In written comments on our draft report, Mercy disagreed with our findings for all but two claims (one homebound and one skilled need). Mercy generally disagreed with our first recommendation and partially agreed with our second and third recommendations. For the first recommendation, to refund overpayments for incorrectly billed claims that are within the reopening period, Mercy generally disagreed with our medical review determinations and maintained that 21 of the 23 sample claims were billed correctly. Mercy stated that there were errors in the application of Medicare coverage and payment policies, which was a result of a flawed audit process. Mercy further stated that extrapolation is inappropriate for a low error rate and, regardless, is not appropriate until “final determination[s]” are made on appeal.

For the second recommendation, to exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule and identify any of those returned overpayments, Mercy stated that it has conducted a thorough review of “the medical records at issue” and determined that, with the exception of 2 claims, the services met all Medicare program requirements and were appropriately billed.¹⁵ For the third recommendation, to strengthen its procedures to ensure that (1) the homebound statuses of Medicare beneficiaries are verified and continually monitored and the specific factors qualifying beneficiaries as homebound are documented and (2) beneficiaries are receiving only reasonable and necessary skilled services, Mercy stated that there are always opportunities for improvement in internal controls. Mercy stated that it maintains a fully mature Integrity & Compliance Program that fully meets regulatory standards and guidelines and that no additional internal controls are needed.¹⁶

We have included Mercy’s comments in their entirety as Appendix F.

¹⁵ Mercy stated that it believes it complied with the 60-Day Rule because it reviewed just the claims we questioned, found only two to have been in error, and intends to appeal the remaining claims we questioned. The OIG continues to believe that this audit report constitutes credible information of potential overpayments and we remind Mercy that the lookback period for the 60-Day Rule is six years. 42 CFR § 401.305(f).

¹⁶ Mercy believes that no additional internal controls are needed based on its conclusion that only two claims in our sample were in error. As stated below, we maintain that our findings (23 claims of the 100 sampled were in error) and third recommendation are valid.
Medicare HHA Provider Compliance Audit: Mercy Health Visiting Nurse Services (A-05-18-00035)

OFFICE OF INSPECTOR GENERAL RESPONSE

After reviewing Mercy's response and further considering our medical review results, we acknowledge Mercy's corrective actions taken thus far, however, we maintain that our findings and recommendations are valid. Below is a summary of the reasons Mercy did not agree with our findings and recommendations and our responses.

OFFICE OF INSPECTOR GENERAL'S AUDIT PROCESS

Mercy contends that our audit process was flawed because it did not have an opportunity to engage in discussions with our contracted medical reviewers. We follow GAGAS requirements, which do not require that auditees be allowed to engage in discussions with specialists retained to assist with Government audits. We followed all GAGAS requirements for using specialists (*e.g.*, contracted medical reviewers) to assist with this audit and Mercy did not contend otherwise. Accordingly, we do not agree with Mercy's contention that our audit process is flawed.

BENEFICIARIES WERE NOT HOMEBOUND

Mercy Comments

Mercy stated that determinations pertaining to noncompliance with homebound requirements were flawed because medical reviewers did not correctly apply Medicare coverage criteria or failed to account for relevant clinical evidence when determining homebound status, or both. Mercy cited examples it believes showed that our medical reviewer impermissibly used ambulation distance as a "rule of thumb" or caregiver availability within the home when determining homebound status. In addition, Mercy stated that the medical reviewers applied invalid and overly narrow criteria for Medicare home health coverage that is not supported by statute or regulation.

Office of Inspector General Response

We disagree with Mercy's assertion that our medical reviewer did not correctly apply Medicare coverage criteria or failed to account for relevant clinical evidence when determining homebound status. Our medical reviewer prepared detailed medical review determination reports documenting relevant clinical evidence and its analysis. OIG provided these reports to Mercy before we issued our draft report. Each determination letter included a detailed set of facts based on a thorough review of the entire medical record. In all cases, our medical reviewer considered the entire record and relied upon the relevant and salient facts necessary to determine homebound status in accordance with CMS's homebound definition.

As shown in each medical review determination report, our medical reviewer documented in detail, the review of the beneficiary's medical history, including diagnoses, skilled nursing or therapy assessments, cognitive function, and mobility for each beneficiary. Ambulation

distance is one factor among others that our medical reviewer considered in making homebound determinations. In terms of meeting CMS homebound criteria, medical review determinations must be based on each patient's individual characteristics as reflected in the available record. Our medical reviewer carefully considered ability to ambulate in conjunction with the individual characteristics noted in each patient's medical record. Ambulation distance was not noted in all decisions, and when it was, it was simply one factor the reviewer considered in making the homebound determination. This is evident from the relevant facts and discussion included in the individual decisions.

In addition, our medical reviewer noted in several cases that caregiver assistance was available, however this was not a factor in determining whether the patient was homebound.

BENEFICIARIES DID NOT REQUIRE SKILLED SERVICES

Mercy Comments

Mercy stated that medical review decisions related to medical necessity of skilled services were based on applying improper coverage standards of Medicare coverage criteria for home health services. Mercy cited examples of determination letters in which beneficiaries were described as having "chronic" or "longstanding" conditions, which it believes demonstrates that our medical reviewer applied improper coverage standards. Mercy also stated that our medical reviewers appeared to have ignored documentation clearly supporting the medical necessity of skilled nursing care for observation and assessment when a beneficiary presented a high risk of complications.

Office of Inspector General Response

Our medical reviewer determined the medical necessity of skilled nursing care and skilled therapy services in accordance with the Manual, chapter 7, sections 40.1 and 40.2, respectively. These Manual provisions state:

Skilled Nursing Care

A patient's overall medical condition, without regard to whether the illness or injury is acute, chronic, terminal, or expected to extend over a long period of time, should be considered in deciding whether skilled services are needed. A patient's diagnosis should never be the sole factor in deciding that a service the patient needs is either skilled or not skilled.

Skilled Therapy Services

While a patient's particular medical condition is a valid factor in deciding if skilled therapy services are needed, a patient's diagnosis or prognosis should never be the sole factor in deciding that a service is or is not skilled. The key issue is

whether the skills of a therapist are needed to treat the illness or injury, or whether the services can be carried out by unskilled personnel.

Moreover, as we noted in footnote 11, skilled nursing services can include observation and assessment of a patient's condition, management and evaluation of a patient plan of care, teaching and training activities, and administration of medications, among other things (the Manual, chapter 7, § 40.1.2).

In questioning the need for skilled therapy services, our medical reviewer noted in two instances that patients had, among other things, "chronic stable dementia" or "chronic stable cognitive deficits". Our medical reviewer did not use the term "longstanding" in any of their denials for skilled services. That our medical reviewer accurately noted in determination letters that some of the patients' conditions may have been chronic does not, however, demonstrate that he or she failed to consider each patient's overall condition without regard to whether the illness or injury is acute, chronic, terminal, or expected to extend over a long period of time. In each instance, our medical reviewer made note of several illnesses or injuries, some of which were chronic, some of which were acute, but all contributed to the patient's overall medical condition. Therefore, we disagree with Mercy's assertion that our medical reviewer applied improper coverage standards in determining the medical necessity of skilled services.

In addition, we disagree with Mercy's assertion that our medical reviewer ignored documentation supporting the medical necessity of skilled nursing services. In determining the medical necessity of skilled nursing services, our medical reviewer considered the patient's clinical condition and whether skilled services were necessary to safely and effectively maintain the patient's current condition or slow further deterioration pursuant to the Manual, chapter 7, § 40.1.1. Per these CMS guidelines, when the services provided could be safely and effectively performed by the patient or unskilled caregivers, such services will not be covered under the home health benefit.

ALTERNATIVE PAYMENT MODELS

Mercy Comments

Mercy stated that due to its participation in two Medicare Alternative Payment Models (APMs) sponsored by CMS during the audit period, some claims under review should have been excluded from our audit. The sample contained 29 claims that were part of an APM and, of those, 9 claims had reported errors reflecting \$15,862 in overpayments. Mercy stated that none of those claims should be considered "payment errors" and be subject to repayment or included in any extrapolation of estimated overpayments.

Office of Inspector General Response

We disagree that some claims in the sampling frame should be excluded from OIG review. The sampled claims were paid under the Medicare fee-for-service payment method and therefore are subject to OIG review. CMS guidance states that those participating APMs will still be

subject to the existing level of oversight from other review programs, including OIG reviews.¹⁷ In addition, the APM participation agreements state that none of the provisions of the agreements limit or restrict OIG's authority to audit, evaluate, investigate, or inspect the accountable care organization or its participants and preferred providers.

USE OF EXTRAPOLATION

Mercy Comments

Mercy contends that it is inappropriate to use extrapolation at this time. Mercy noted that Medicare contractors cannot use extrapolation unless (1) there is a sustained or high level of payment error or (2) there is a failure of documented educational interventions. Mercy stated that extrapolation would be allowed under applicable statute only if a final, non-appealed determination on the claims at issue is found to demonstrate a high error rate. Mercy said that it appreciates that CMS policies are not binding on OIG. Mercy stated that the Medicare contractor that processes any associated overpayments connected to the audit will be subject to CMS policies, and these rules directly bear on the questions of whether CMS may accept OIG's findings on the amount of the alleged overpayments. Mercy stated that it intends to exhaust all Medicare administrative appeals for the disputed claims, which consist of 21 of the 23 claims found to be in error with overpayments. In addition, Mercy said extrapolation is particularly unwarranted since virtually all the claim denials relate to medical necessity issues.

Office of Inspector General Response

Federal courts have consistently upheld statistical sampling and extrapolation as valid means to determine overpayment amounts in Medicare and Medicaid.¹⁸ The legal standard for use of sampling and extrapolation is that it must be based on a statistically valid methodology.¹⁹ We properly executed our statistical sampling methodology in that we defined our sampling frame and sampling unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical sampling software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation. The statistical lower limit that we use for our recommended recovery represents a conservative estimate of the overpayment that we would have identified if we had

¹⁷ See CMS Announcement "Reducing Medical Record Review for Clinicians Participating in Certain Advanced Alternative Payment Models" at <https://www.cms.gov/newsroom/factsheets/reducing-medical-record-review-clinicians-participating-certain-advanced-alternative-payment-models>.

¹⁸ See *Yorktown Med. Lab., Inc. v. Perales*, 948 F.2d 84 (2d Cir. 1991); *Illinois Physicians Union v. Miller*, 675 F.2d 151 (7th Cir. 1982); *Momentum EMS, Inc. v. Sebelius*, 2013 U.S. Dist. LEXIS 183591 at *26-28 (S.D. Tex. 2013), adopted by 2014 U.S. Dist. LEXIS 4474 (S.D. Tex. 2014); *Anghel v. Sebelius*, 912 F. Supp. 2d 4 (E.D.N.Y. 2012); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 (S.D. Fla. 2012); *Bend v. Sebelius*, 2010 U.S. Dist. LEXIS 127673 (C.D. Cal. 2010).

¹⁹ See *John Balko & Assoc. v. Sebelius*, 2012 WL 6738246 at *12 (W.D. Pa. 2012), *aff'd* 555 F. App'x 188 (3d Cir. 2014); *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 634-37 (W.D. Tex. 2016), *aff'd*, 860 F.3d 335 (5th Cir. 2017); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 18 (E.D.N.Y. 2012); *Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at *13 (S.D. Tex. 2012).

reviewed each and every claim in the sampling frame. The conservative nature of our estimate is not changed by the nature of the medical necessity errors identified in this audit. Moreover, the court case that Mercy referenced in support of the proposition that extrapolation is inappropriate for issues of medical necessity, United States ex rel. Wall v. Vista Hospice Care, Inc., 2016 U.S. Dist. LEXIS 80160, 2016 WL 3449833 (N.D. Tex. 2016), is limited to False Claims Act cases in northern Texas and is inapplicable to OIG audit recommendations and CMS recoveries arising from OIG audits. In addition, the U.S. Court of Appeals for the Fifth Circuit expressly refuted Mercy's contention, stating:

To the extent that [the provider] raises a broader claim that extrapolation is inappropriate where medical necessity is at issue, that claim also fails. As numerous courts have held, extrapolating from a randomly selected sample of paid claims presents a "fairly low risk of error" in calculating the ultimate overpayment amount (Dominion Ambulance v. Azar, 2020 U.S. App LEXIS 24399, *21 (5th Cir 2020)).

The requirement that a determination of a sustained or high level of payment error or documented failed educational intervention must be made before extrapolation applies only to Medicare contractors.²⁰ The Medicare Program Integrity Manual (PIM) and the statutory provisions upon which the PIM guidelines are based do not prohibit CMS from accepting and acting upon our monetary recommendation.

²⁰ See Social Security Act § 1893(f)(3) and CMS Medicare Program Integrity Manual, Pub. No. 100-08, ch. 8.4, § (effective January 2, 2019).

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered \$10,723,568 in Medicare payments to Mercy for 3,894 home health claims with episode-of-care through dates in CYs 2016 and 2017. From this sampling frame, we selected for review a simple random sample of 100 home health claims with payments totaling \$284,285.

We evaluated compliance with selected billing requirements and submitted the sampled claims to an independent medical review contractor to determine whether the services met coverage, medical necessity, and coding requirements.

We limited our review of Mercy's internal controls to those applicable to specific Medicare billing procedures because our objective did not require an understanding of all internal controls over the submission and processing of claims. We established reasonable assurance of the authenticity and accuracy of the data obtained from CMS's NCH file, but we did not assess the completeness of the file.

We conducted our audit from April 2018 through June 2020.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- extracted Mercy's paid claims data from CMS's NCH file for the audit period;
- removed payments for low utilization payment adjustments, partial episode payments, and requests for anticipated payments from the population to develop our sampling frame;
- selected a simple random sample of 100 home health claims totaling \$284,285 for detailed review (Appendix C);
- reviewed available data from CMS's Common Working File for the sampled claims to determine whether the claims had been canceled or adjusted;
- obtained and reviewed billing and medical record documentation provided by Mercy to support the claims sampled;
- reviewed sampled claims for compliance with known risk areas;

- used an independent medical review contractor to determine whether the 100 claims contained in the sample were reasonable and necessary and met Medicare coverage and coding requirements;
- reviewed Mercy's procedures for billing and submitting Medicare claims;
- verified State licensure information for selected medical personnel providing services to the patients in our sample;
- calculated the correct payments for those claims requiring adjustments;
- used the results of the sample to estimate the total Medicare overpayments to Mercy for our audit period (Appendix D); and
- discussed the results of our audit with Mercy officials.

We conducted this performance audit in accordance with GAGAS. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

APPENDIX B: MEDICARE REQUIREMENTS FOR COVERAGE AND PAYMENT OF CLAIMS FOR HOME HEALTH SERVICES

GENERAL MEDICARE REQUIREMENTS

Medicare payments may not be made for items and services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member” (the Act § 1862(a)(1)(A)).

CMS’s Medicare Claims Processing Manual, Pub. No. 100-04, states: “In order to be processed correctly and promptly, a bill must be completed accurately” (chapter 1 § 80.3.2.2).

OUTCOME AND ASSESSMENT INFORMATION SET DATA

The OASIS is a standard set of data elements that HHA clinicians use to assess the clinical needs, functional status, and service utilization of a beneficiary receiving home health services. CMS uses OASIS data to assign beneficiaries to the appropriate categories, called case-mix groups; to monitor the effects of treatment on patient care and outcomes; and to determine whether adjustments to the case-mix groups are warranted. HHA beneficiaries can be classified into 153 case-mix groups that are used as the basis for the HIPPS rate codes Medicare uses in its prospective payment systems. Case-mix groups represent specific sets of patient characteristics and are designed to classify patients who are similar clinically in terms of resources used.

CMS requires the submission of OASIS data as a condition of payment as of January 1, 2010 (42 CFR § 484.210(e)); 74 Fed. Reg. 58078, 58110 (Nov. 10, 2009); and CMS’s *Medicare Program Integrity Manual*, Pub. No. 100-08, chapter 3, § 3.2.3.1.

COVERAGE AND PAYMENT REQUIREMENTS

To qualify for home health services, Medicare beneficiaries must (1) be homebound; (2) need intermittent skilled nursing care (other than solely for venipuncture for the purpose of obtaining a blood sample) or physical therapy, speech-language pathology, or occupational therapy;²¹(3) be under the care of a physician; and (4) be under a plan of care that has been established and periodically reviewed by a physician (the Act §§ 1814(a)(2)(C) and 1835(a)(2)(A), 42 CFR § 409.42, and the Manual, chapter 7, § 30).

²¹ Effective January 1, 2012, CMS clarified the status of occupational therapy to reflect when it becomes a qualifying service rather than a dependent service. Specifically, the first occupational therapy service, which is a dependent service, is covered only when followed by an intermittent skilled nursing care service, a physical therapy service, or a speech-language pathology service as required by law. Once the requirement for covered occupational therapy has been met, however, all subsequent occupational therapy services that continue to meet the reasonable and necessary statutory requirements are considered qualifying services in both the current and subsequent certification periods (subsequent adjacent episodes) (76 Fed. Reg. 68526, 68590 (Nov. 4, 2011)).

Per the Manual, chapter 7, section 20.1.2, whether care is reasonable and necessary is based on information reflected in the home health plan of care, the OASIS, or a medical record of the individual patient.

The Act and Federal regulations state that Medicare pays for home health services only if a physician certifies that the beneficiary meets the above coverage requirements (the Act §§ 1814(a)(2)(C) and 1835(a)(2)(A) and 42 CFR § 424.22(a)).

Section 6407(a) of the Affordable Care Act²² added a requirement to sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act that the physician have a face-to-face encounter with the beneficiary. In addition, the physician responsible for performing the initial certification must document that the face-to-face patient encounter, which is related to the primary reason the patient requires home health services, has occurred no more than 90 days before the home health start-of-care date or within 30 days of the start of the home health care by including the date of the encounter.²³

Confined to the Home

For reimbursement of home health services, the beneficiary must be “confined to the home” (the Act §§ 1814(a)(2)(C) and 1835(a)(2)(A)) and Federal regulations (42 CFR § 409.42). According to section 1814(a) of the Act:

[A]n individual shall be considered to be “confined to his home” if the individual has a condition, due to illness or injury, that restricts the ability of the individual to leave his or her home except with the assistance of another individual or the aid of a supportive device (such as crutches, a cane, a wheelchair, or a walker), or if the individual has a condition such that leaving his or her home is medically contraindicated. While an individual does not have to be bedridden to be considered “confined to his home,” the condition of the individual should be such that there exists a normal inability to leave home and that leaving home requires a considerable and taxing effort by the individual.

CMS provided further guidance and specific examples in the Manual (chapter 7 § 30.1.1). The Manual states that for a patient to be eligible to receive covered home health services under both Part A and Part B, the law requires that a physician certify in all cases that the patient is

²² The Patient Protection and Affordable Care Act, P.L. No. 111-148 (Mar. 23, 2010), as amended by the Health Care and Education Reconciliation Act of 2010, P.L. No. 111-152 (Mar. 30, 2010), collectively known as the Affordable Care Act.

²³ See 42 CFR § 424.22(a)(1)(v) and the Manual, chapter 7, § 30.5. The initial effective date for the face-to-face requirement was January 1, 2011. However, on December 23, 2010, CMS granted HHAs additional time to establish protocols for newly required face-to-face encounters. Therefore, documentation regarding these encounters must be present on certifications for patients with starts of care on or after April 1, 2011.

confined to his or her home. For purposes of the statute, an individual must be considered “confined to the home” (homebound) if the following two criteria are met:

Criteria One

The patient must either:

- because of illness or injury, need the aid of supportive devices such as crutches, canes, wheelchairs, and walkers; the use of special transportation; or the assistance of another person in order to leave his or her place of residence; or
- have a condition such that leaving his or her home is medically contraindicated.

If the patient meets one of the Criteria One conditions, then the patient must also meet two additional requirements defined in Criteria Two below.

Criteria Two

There must exist a normal inability to leave home, and leaving home must require a considerable and taxing effort.

Need for Skilled Services

Intermittent Skilled Nursing Care

To be covered as skilled nursing services, the services must require the skills of a registered nurse or a licensed practical (vocational) nurse under the supervision of a registered nurse; must be reasonable and necessary to the treatment of the patient’s illness or injury; and must be intermittent (42 CFR § 409.44(b) and the Manual, chapter 7, § 40.1).

The Act defines “part-time or intermittent services” as skilled nursing and home health aide services furnished any number of days per week as long as they are furnished (combined) less than 8 hours each day and 28 or fewer hours each week (or, subject to review on a case-by-case basis as to the need for care, less than 8 hours each day, and 35 or fewer hours each week) (the Act § 1861(m) and the Manual, chapter 7, § 50.7).

Requiring Skills of a Licensed Nurse

Federal regulations (42 CFR § 409.44(b)) state that in determining whether a service requires the skill of a licensed nurse, consideration must be given to the inherent complexity of the service, the condition of the beneficiary, and accepted standards of medical and nursing practice. If the nature of a service is such that it can be safely and effectively performed by the average nonmedical person without direct supervision of a licensed nurse, the service may not be regarded as a skilled nursing service. The fact that a skilled nursing service can be or is

taught to the beneficiary or to the beneficiary's family or friends does not negate the skilled aspect of the service when performed by the nurse. If the service could be performed by the average nonmedical person, the absence of a competent person to perform it does not cause it to be a skilled nursing service.

General Principles Governing Reasonable and Necessary Skilled Nursing Care

Skilled nursing services are covered when an individualized assessment of the patient's clinical condition demonstrates that the specialized judgment, knowledge, and skills of a registered nurse or licensed practical (vocational) nurse are necessary to maintain the patient's current condition or prevent or slow further deterioration so long as the beneficiary requires skilled care for the services to be safely and effectively provided.

Some services may be classified as a skilled nursing service on the basis of complexity alone (e.g., intravenous and intramuscular injections or insertion of catheters) and, if reasonable and necessary to the patient's illness or injury, would be covered on that basis. If a service can be safely and effectively performed (or self-administered) by an unskilled person, without the direct supervision of a nurse, the service cannot be regarded as a skilled nursing service even though a nurse actually provides the service. However, in some cases, the condition of the patient may cause a service that would ordinarily be considered unskilled to be considered a skilled nursing service. This would occur when the patient's condition is such that the service can be safely and effectively provided only by a nurse. A service is not considered a skilled service merely because it is performed by or under the supervision of a nurse. The unavailability of a competent person to provide a nonskilled service does not make it a skilled service when a nurse provides the service.

A patient's overall medical condition, without regard to whether the illness or injury is acute, chronic, terminal, or expected to extend over a long period of time, should be considered in deciding whether skilled services are needed. A patient's diagnosis should never be the sole factor in deciding that a service the patient needs is either skilled or not skilled. Skilled care may, depending on the unique condition of the patient, continue to be necessary for patients whose condition is stable (the Manual, chapter 7, § 40.1.1).

Reasonable and Necessary Therapy Services

Federal regulations (42 CFR § 409.44(c)) and the Manual (chapter 7 § 40.2.1) state that skilled services must be reasonable and necessary to the treatment of the patient's illness or injury or to the restoration or maintenance of function affected by the patient's illness or injury within the context of the patient's unique medical condition. To be considered reasonable and necessary for the treatment of the illness or injury, the therapy services must be:

- inherently complex, which means that they can be performed safely and effectively only by or under the general supervision of a skilled therapist;

- consistent with the nature and severity of the illness or injury and the patient's particular medical needs, which include services that are reasonable in amount, frequency, and duration; and
- considered specific, safe, and effective treatment for the patient's condition under accepted standards of medical practice.

Documentation Requirements

Face-to-Face Encounter

Federal regulations (42 CFR § 424.22(a)(1)(v)) and the Manual (chapter 7 § 30.5.1) state that, prior to initially certifying the home health patient's eligibility, the certifying physician must document that he or she, or an allowed nonphysician practitioner, had a face-to-face encounter with the patient that is related to the primary reason the patient requires home health services. In addition, the Manual (chapter 7 § 30.5.1) states that the certifying physician must document the encounter either on the certification, which the physician signs and dates, or a signed addendum to the certification.

Plan of Care

The orders on the plan of care must indicate the type of services to be provided to the patient, both with respect to the professional who will provide them and the nature of the individual services, as well as the frequency of the services (the Manual, chapter 7, § 30.2.2). The plan of care must be reviewed and signed by the physician who established the plan of care, in consultation with HHA professional personnel, at least every 60 days. Each review of a patient's plan of care must contain the signature of the physician and the date of review (42 CFR § 409.43(e) and the Manual, chapter 7, § 30.2.6).

APPENDIX C: SAMPLE DESIGN AND METHODOLOGY

SAMPLE FRAME

For CYs 2016 and 2017, Mercy received Medicare payments of \$11,596,417 for 4,972 home health services provided to Medicare beneficiaries. We excluded 1,078 home health service claims.²⁴ The sampling frame consisted of a database of 3,894 home health claims, valued at \$10,723,568, from CMS's NCH file.

SAMPLE UNIT

The sample unit was a home health claim.

SAMPLE DESIGN AND SAMPLE SIZE

We used a simple random sample and randomly selected 100 sample units.

SOURCE OF RANDOM NUMBERS

We generated the random numbers using the OIG, Office of Audit Services (OAS), statistical software.

METHOD FOR SELECTING SAMPLE ITEMS

We consecutively numbered the sample units, and after generating the random numbers, we selected the corresponding frame items for audit.

ESTIMATION METHODOLOGY

We used the OIG/OAS statistical software to estimate the total amount of any overpayments paid to Mercy during the audit period. To be conservative, we recommend recovery of overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

²⁴ We excluded home health payments for low utilization adjustments, partial episode payments, and requests for anticipated payments. We also excluded claims that resulted in error code 534 when matched against the Recovery Audit Contractor Data Warehouse. This code represents claims that have already been marked for exclusion by an OIG audit, investigation, or similar review.

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Table 1: Sample Results

Frame Size	Total Value of Frame	Sample Size	Total Value of Sample	Incorrectly Billed Sample Items	Value of Overpayments in Sample
3,894	\$10,723,568	100	\$284,285	23	\$42,466

**Table 2: Estimates of Overpayments for the Audit Period
(Limits Calculated for a 90-Percent Confidence Interval)**

Point estimate	\$1,653,631
Lower limit	1,074,136
Upper limit	2,233,127

APPENDIX E: TYPES OF ERRORS BY SAMPLE ITEM

SAMPLES 1–25

Sample	Not Homebound	Did Not Require Skilled Services	Overpayment
1	-	-	-
2	-	-	-
3	-	-	-
4	-	-	-
5	-	-	-
6	X	X	\$2,376
7	-	-	-
8	X	-	1,781
9	-	-	-
10	-	-	-
11	-	-	-
12	-	-	-
13	-	-	-
14	-	-	-
15	X	-	2,709
16	-	-	-
17	-	-	-
18	-	-	-
19	-	-	-
20	-	-	-
21	-	X	656
22	-	-	-
23	-	-	-
24	-	-	-
25	-	-	-

SAMPLES 26–50

Sample	Not Homebound	Did Not Require Skilled Services	Overpayment
26	-	-	-
27	-	-	-
28	-	-	-
29	-	-	-
30	-	-	-
31	-	-	-
32	-	X	\$311
33	-	-	-
34	-	-	-
35	-	-	-
36	-	-	-
37	-	-	-
38	X	-	1,075
39	-	-	-
40	-	-	-
41	-	-	-
42	-	-	-
43	-	-	-
44	-	-	-
45	X	X	3,142
46	X	-	328
47	-	-	-
48	-	-	-
49	-	-	-
50	-	-	-

SAMPLES 51-75

Sample	Not Homebound	Did Not Require Skilled Services	Overpayment
51	-	-	-
52	-	-	-
53	-	-	-
54	-	-	-
55	X	-	\$2,282
56	-	-	-
57	-	-	-
58	-	-	-
59	-	-	-
60	-	-	-
61	-	-	-
62	-	-	-
63	-	X	684
64	-	-	-
65	-	-	-
66	-	-	-
67	-	-	-
68	-	-	-
69	-	-	-
70	-	-	-
71	-	-	-
72	-	-	-
73	X	X	2,331
74	X	X	2,934
75	-	-	-

SAMPLES 76–100

Sample	Not Homebound	Did Not Require Skilled Services	Overpayment
76	-	-	-
77	-	-	-
78	-	-	-
79	-	X	\$1,635
80	X	-	394
81	-	-	-
82	X	X	2,224
83	-	-	-
84	-	X	781
85	X	X	2,188
86	-	-	-
87	X	X	2,555
88	X	X	2,231
89	-	-	-
90	X	X	3,063
91	-	-	-
92	-	-	-
93	-	X	1,567
94	-	X	3,607
95	-	-	-
96	-	-	-
97	X	-	1,612
98	-	-	-
99	-	-	-
100	-	-	-
Total	16	16	\$42,466²⁵

²⁵ The sum of the column does not equal the total amount due to rounding.

APPENDIX F: MERCY HEALTH VISITING NURSE SERVICES COMMENTS



May 29, 2020

Sheri L. Fulcher
Regional Inspector General for Audit Services Office
of Audit Services, Region V
233 North Michigan, Suite 1360
Chicago, IL 60601

RE: Medicare Home Health Agency Provider Compliance Audit: Mercy Health Visiting Nurse Services,
OIG Report No: A-05-18-00035

Dear Ms. Fulcher:

Trinity Health at Home ("THAH"), on behalf of Mercy Health Visiting Nurse Services ("Mercy Health VNS"), a wholly-controlled subsidiary of THAH, appreciates the opportunity to submit this letter in response to the preliminary findings of the Department of Health and Human Services Office of Inspector General ("HHS OIG") Medicare Home Health Agency Provider Compliance Audit of Mercy Health VNS. THAH takes seriously its obligations to ensure all Medicare home health coverage and billing requirements are fully met and acknowledges the important role HHS OIG plays in oversight of these obligations. We understand the audit was conducted as part of a series of home health services compliance reviews performed in recent years by HHS OIG focusing on areas deemed by HHS OIG to be at-risk of noncompliance with Medicare billing requirements and was not triggered by any specific concerns with Mercy Health VNS billing practices.

HHS OIG's preliminary findings are contained in the draft report dated March 24, 2020 (the "Draft Audit Report"). HHS OIG's stated objective of the audit was to determine if Mercy Health VNS complied with Medicare requirements for home health services for 100 selected claims paid during calendar years 2016 and 2017. The principal findings contained in the Draft Audit Report are as follows:

- Mercy Health VNS did not comply with Medicare billing requirements for 23 of 100 home health claims reviewed, resulting in net overpayments of \$42,466;
- Specifically, HHS OIG determined Mercy Health VNS incorrectly billed Medicare for 1) services provided to beneficiaries who were not homebound; and 2) services provided to beneficiaries who did not require skilled services;
- Based on this determination, HHS OIG estimated Mercy Health VNS received overpayments of at least \$1,074,136 for the audit period. HHS OIG concedes that this amount does not represent a final determination of an overpayment, and the responsibility for determining whether an overpayment exists, and recoupment of any overpayments is the responsibility of the Centers for Medicare and Medicaid Services ("CMS").

- HHS OIG recommends Mercy Health VNS refund to the Medicare program the portion of the estimated \$1,074,136 for claims incorrectly billed that are within the four-year reopening period;
- HHS OIG further recommends Mercy Health VNS exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-Day Repayment Rule,¹ and identify any of those returned overpayments as having been made in accordance with HHS OIG's recommendation; and
- HHS OIG recommends Mercy Health VNS strengthen its procedures to ensure full compliance with Medicare requirements for homebound status and skilled services.

As further described herein, THAH disagrees with all but two (2) of the findings in the Draft Audit Report. THAH contends the Draft Report contains significant errors in the application of Medicare coverage and payment policies which should be corrected prior to issuance of a final report. We believe these errors are a result of a flawed audit process that did not provide an opportunity for THAH to engage in substantive discussions on the merits of HHS OIG's findings directly with the contracted medical reviewers. HHS OIG representatives participating in meetings with THAH acknowledged they did not possess the necessary clinical or home health industry expertise to respond directly to THAH's questions concerning the audit findings, including the basis by which certain claims were determined to have not met Medicare coverage and billing requirements. HHS OIG representatives in the meetings deferred to the findings of the contract medical reviewers.

At the audit exiting meeting on August 2, 2019, THAH requested the opportunity to speak directly with HHS OIG's contracted medical reviewers to discuss the audit findings in order to further understand the basis upon which the medical reviewers made their determinations and to correct numerous substantive errors THAH believes were made in the audit. To date HHS OIG has declined to make the medical reviewers available to speak with THAH. Following the audit exit meeting, THAH submitted a detailed written response to HHS OIG citing our disagreements with the audit findings for each claim found in error by the medical reviewers. Our response cited specific examples where THAH believes the contracted medical reviewers incorrectly applied Medicare coverage and payment policies. We are disappointed that our written response does not appear to have resulted in any change to the findings contained in the Draft Audit Report.

The following is a summary with examples of THAH's principle disagreements with HHS OIG's audit findings.

Beneficiaries Were Not Homebound

HHS OIG's medical reviewers determined that Mercy Health VNS incorrectly billed Medicare for home health episodes for beneficiaries who did not meet federal homebound requirements in 16 of 100 claims reviewed. Eleven (11) claims were denied for the full episode of care, and 5 claims were denied for a portion of an episode. As explained further below, THAH disagrees with HHS OIG's findings for 15 of the 16 cases identified as errors.

¹ The 60-Day Repayment Rule is codified at 1128J(d) of the Social Security Act and 42 C.F.R. Part 401, Subpart D.

HHS OIG's medical reviewers repeatedly based their decisions that beneficiaries did not meet homebound requirements due to the patient's ability to ambulate certain distances in the home with or without an assistive device (e.g., walker, cane). By way of example, OIG stated the following in Sample 15:

"The medical information does not support that the patient was homebound at the start of care. As of 1/23/17, he was able to ambulate 350 feet with contact guard assistance. He required standby assistance for performing transfers. He had been progressed to stairclimbing and was able to negotiate eight steps. He was living with his son and daughter and there was caregiver assistance available."

Ability to Ambulate

HHS OIG cited the patient's ability to ambulate a certain distance during therapy visits as the basis for concluding the beneficiary was not homebound. In doing so, HHS OIG has applied an improper coverage standard that has no basis in law, regulations or CMS guidance, and is also clinically inappropriate. Neither the statute nor CMS guidelines defining "homebound" require a beneficiary to be bedridden, nor do they require a beneficiary be unable to ambulate certain distances. In fact, CMS acknowledges that occasional absences from the home for non-medical purposes does not disqualify a beneficiary's homebound status provided that doing so requires considerable and taxing effort. Noting in the Medicare rules suggest it is permissible to discount homebound status based on the number of feet a patient can ambulate in the home.

CMS regulations also state that home health coverage decisions must be made on objective, clinical evidence regarding the beneficiary's individual need for care.² CMS specifically disallow determinations based on numerical utilization screens and "Rules of Thumb."³ Any presumption or general precondition that fails to take into account a beneficiary's individual care needs constitutes an improper "rule of thumb." A decision that a beneficiary is not homebound because he or she can ambulate a certain distance constitutes a presumption unrelated to the beneficiary's unique clinical condition and creates a new coverage requirement for home health services. Furthermore, the fact that a beneficiary may be able to ambulate for 100 or 200 feet during a therapy session inside the home (or a facility), with supervision or assistance from a licensed therapist and with use of an assistive device, does not demonstrate that the beneficiary possesses sufficient functional mobility to leave home safely, independently, and on a regular basis.

Taken in isolation, a patient's ability to ambulate certain distances might suggest that leaving the home is not taxing. But this information cannot be viewed in a vacuum without consideration of the beneficiary's complete medical record. In Sample 15 cited previously, the medical record documentation notes the patient was 96 years old, deaf in one ear, with impaired vision due to cataracts. The patient had recently been hospitalized for treatment of a renal calculus and ambulated with a walker due to a broken hip sustained earlier in the year. Other co-morbid conditions documented included pneumonia and Alzheimer's dementia. It appears HHS OIG's medical reviewers failed to consider the entirety of the beneficiary's medical record in making its determination that homebound status was not met. The combination of the patient's acute medical incident, chronic conditions, and cognitive and physical limitations clearly support that leaving home was unsafe and would have required a considerable and taxing effort.

Caregiver Availability

² 42 C.F.R. §409.44(a)

³ Medicare Benefit Policy Manual Ch. 7 §20.3

In addition to the ability to ambulate, HHS OIG's reviewers also cited in Sample 15, and several other cases, the availability of other caregivers in the home as a factor in determining that homebound status was not met. CMS regulations state that a patient is entitled to home care services without regard to whether there is someone available to furnish services.⁴ The need for the assistance of another person in order to leave the home or place of residence is one of two criteria supporting a patient's homebound status.

CMS requires the determination of a beneficiary's homebound status be made by a licensed physician who must assess the beneficiary's condition through a face-to-face medical evaluation after having undertaken a review of the beneficiary's medical history.⁵ It is of great concern that HHS OIG's reviewers cited a Medicare patient's ability to ambulate in the home, as well as availability of other caregivers in certain cases, as the primary basis for its decisions that homebound status was not met in numerous cases (see samples S-6, S-8, S-38, S-45, S-46, S-55, S-73, S-74, S-82, S-85, S-87, S-88, S-90, and S-97). In doing so, HHS OIG's reviewers have applied invalid and overly narrow criteria for Medicare home health coverage that is not supported by statute or regulation. As noted previously, THAH was unable to discuss these issues directly with HHS OIG's medical reviewers before the Draft Audit Report was finalized. However, THAH is confident a significant majority of HHS OIG's findings regarding homebound status will be overturned upon appeal with CMS.

THAH agrees with HHS OIG's finding in Sample 80 that the Medicare beneficiary was no longer homebound for a portion of the episode of care. THAH has taken steps to refund the partial overpayment on this claim of \$393.76 to its Medicare contractor.

Beneficiaries Did Not Require Skilled Services

In 16 of 100 cases reviewed, HHS OIG's medical reviewers determined the beneficiaries did not require skilled care for either a portion or entire duration of the home health episode of care. THAH disagrees with HHS OIG's findings in 15 of the 16 claims reported as errors in this category.

Beneficiary Condition

As with the claims denied for homebound status, the medical reviewers appear to have applied improper coverage standards in reaching their conclusions that skilled care was not medically necessary. In certain cases, HHS OIG reviewers focused on the "chronic" or longstanding nature of the beneficiaries' conditions in reaching their determinations. For example, in Samples 21 and 63, the reviewers stated the following in each case:

"There was no clear need for speech therapy. There was no history of recent aspiration pneumonia and the patient had chronic stable cognitive deficits without new impairing condition or neurological injury."

The issue of whether a beneficiary's condition or diagnosis is acute or chronic is irrelevant to whether the beneficiary qualifies for intermittent skilled care under the home health benefit. Medicare regulations state "The determination of whether skilled nursing care is reasonable and necessary must be based solely upon the beneficiary's unique condition and individual needs, without regard to whether the injury is acute, chronic, terminal, or expected to last a long time."⁶ In both Samples 21 and 63, the plans of care and speech therapy

⁴ MBPM Ch. 7 §20.2

⁵ 42 U.S.C. §1395n(a)(2)(A)

⁶ 42 C.F.R. § 409.44(b)(3)(iii)

evaluations clearly documented the need for speech therapy. For example, in Sample 63 the patient had experienced atrial fibrillation following hospitalization with concerns reported regarding the patient's memory. The patient had been independent with medications prior to the hospitalization, but now required family assistance. The speech therapy evaluation clearly documented cognition as a new impairment supporting the need for speech therapy.

Medical Necessity Documentation in the Records

In other instances, HHS OIG's medical reviewers appeared to have ignored documentation clearly supporting the medical necessity of skilled nursing services for observation and assessment when a beneficiary presented a high risk of complications. For example, in Sample 74, the reviewers stated the following:

"However, skilled nursing was medically unnecessary. The patient had diabetes but self-managed it without complications. She was hospitalized secondary to a low sodium but had no signs or symptoms. Her wound was clean dry and closed. She did not require monitoring, observation or skilled nursing intervention."

The medical records for Sample 74 describe the patient as a 73-year old female who was debilitated following an inpatient stay for Sternal Split and Thymectomy due to syndrome of inappropriate antidiuretic hormone due to malignant neoplasm of thymus. The patient had a history of hypomagnesemia, COPD, Bartholin cyst with abscess, dyslipidemia, dysphasia with dental issues, and hemoptysis with history of smoking. Skilled nursing was needed to observe and assess vital signs, pain status, oxygen saturation in response to exercise/activity, cardiopulmonary/vascular, GI, GU, integumentary, musculo-skeletal and neuro systems, nutrition/hydration, elimination, symptom management, compliance with treatment plan, response to medication, progress towards increasing functional status, ADL independence, monitoring of incision, respiratory status, and pain. Speech therapy was documented as medically necessary for dysphasia to address excessive drooling that was making it difficult for the beneficiary to communicate, and to reduce food spills by mouth when eating. Occupational therapy was documented as medically necessary to address instructions in maximizing safety/participation in ADL tasks in a new living setting, on the use of needed adaptive equipment, as well as compensatory strategy instruction. The medical necessity for skilled nursing care, speech therapy and occupational therapy services was clearly documented in the patient's medical record. Importantly, this patient's Plan of Care also initially included a referral for physical therapy services. However, the physical therapy was determined to not be necessary following the initial assessment and the patient was discharged from physical therapy.

The above are just three examples of thematic issues found repeatedly in HHS OIG's determinations that claims did not support the need for skilled care. With the one exception noted below, THAH disagrees with the audit findings and is confident a significant majority of HHS OIG's denials related to the need for skilled care will be overturned upon appeal with CMS.

THAH agrees with HHS OIG's finding of a partial denial of payment in Sample 79 as the Medicare beneficiary no longer required physical therapy and speech therapy after certain dates noted in the Draft Audit Report. THAH has taken steps to refund the partial overpayment of \$1,634.54 to its Medicare contractor.

Alternative Payment Models

HHS OIG selected a sample of 100 Medicare claims paid during 2016 - 2017. Through its wholly-owned parent, Trinity Health, THAH participated in two Medicare Alternative Payment Models ("APMs") sponsored by CMS during 2016 – 2017. Trinity Health participated in the Next Generation Accountable Care Organization ("Next Generation Model ACO") through Trinity Health ACO, a wholly-owned Next Generation

Model ACO. Trinity Health also participated in the Bundled Payment for Care Improvement Initiative ("BPCI") as an Episode Initiator. Additional information on both of these APM programs can be found at the following CMS websites:

NextGeneration ACO Model

<https://innovation.cms.gov/innovation-models/next-generation-aco-model> **Bundled**

Payments for Care Improvement (BPCI) Initiative

<https://innovation.cms.gov/innovation-models/bundled-payments>

In both the Next Generation Model ACO and BPCI program, participants, such as Trinity Health, assume greater financial risks for the total cost and outcomes of care provided to Medicare beneficiaries over a specified time period (a calendar year for Next Generation Model ACOs, 90-days of continuous care for a bundled payment episode in BPCI). In both programs, providers submit claims for services and are paid by Medicare on a fee-for-service basis, similar to traditional Medicare. However, in both programs CMS reconciles the total cost of care at the end of the relevant time period to a target cost as established by CMS. Participants that are successful in delivering coordinated, high quality care at lower costs are rewarded by sharing in the savings achieved by Medicare. Participants are also responsible for financial losses if the total cost of care provided to Medicare beneficiaries exceeds the established program targets. CMS reconciles total costs to each program's targeted costs at the end of each respective program's performance period, with settlement of any net amounts due to or owed by participants.

It is important to note that CMS has previously stated that providers participating in Advanced APMs (APMs that feature significant upside and downside financial risk) are considered to be "lower risk" to the Medicare Trust Fund and has previously directed CMS contractors to consider health care providers participating in Advanced APMs to be "low priority" for CMS audits.⁷ The reason for CMS' position is understandable: the potential impact of any billing errors by a health care provider participating in an Advanced APM are largely nullified in a total cost of care financial model where providers bear the financial risks of any billing errors. In Advanced APMs, health care providers like THAH/Trinity Health have no incentive to deliver anything but medically necessary and appropriate care to Medicare beneficiaries.

The HHS OIG audit sample of 100 claims from 2016 and 2017 included 29 claims for Medicare beneficiaries who received home care services from Mercy Health VNS and were either: 1) aligned to Trinity Health ACO; or 2) were included in a Trinity Health BPCI bundled episode of care. Of the 29 claims in the sample, HHS OIG reported errors in 9 claims totaling \$15,862.36 in overpayments. THAH/Trinity Health contends that all claims involving Medicare beneficiaries aligned with Trinity Health ACO or receiving services included in a Trinity Health BPCI bundled payment episode during 2016 and 2017 should be excluded entirely from the HHS OIG audit for the reasons described above. None of these claims should be considered "payment errors" subject to repayment or included in any extrapolation of estimated overpayments.

CMS' reconciliation of Trinity Health's performance in the Next Generation Model ACO and BPCI for years 2016 and 2017 occurred no later than 2018. It would be entirely inappropriate for HHS OIG to assess overpayments on claims audited in the sample connected to these APM programs as if THAH/Trinity Health

⁷ See CMS announcement "*Reducing Medical Record Review for Clinicians Participating in Certain Advanced Alternative Payment Models*" at <https://www.cms.gov/medicare/innovation/alternative-payment-models/announcements/201708-reducing-medical-record-review>

was subject to Medicare fee-for-service payments when, in fact, the services were subject to separate reconciliation by CMS in accordance with these programs. THAH/Trinity Health will pursue all available Medicare administrative appeal rights related to any denied claims and/or extrapolation involving denied claims that were covered under these APMs.

Use of Extrapolation to Estimate \$1.1M Overpayment

In consideration of the disagreements with the audit findings as described herein, THAH contends it is inappropriate to perform an extrapolation at this time. As an initial matter, it should be noted that, by law, Medicare contractors cannot use extrapolation unless 1) there is a sustained or high level of payment error; or 2) there is a failure of documented educational interventions.⁸ CMS has instructed its own contractors that, for purposes of using extrapolation, a sustained or high level of payment error shall be determined to exist when a high error rate determination has been made by the contractor or by other medical reviews (i.e., greater than or equal to 50 percent from a previous pre- or post-payment review)...⁹ In the case of Mercy VNS, the Medicare contractor has not historically found a high level of payment errors of any kind, let alone anything close to 50%. THAH appreciates that CMS policies are not binding on HHS OIG. However, the Medicare contractor that processes any associated overpayments connected to the audit will be subject to CMS policies, and these rules will directly bear on the question of whether CMS can accept OIG's findings as to the amount of the alleged overpayments.

Extrapolation of Overpayment is Inappropriate

Extrapolation would be allowed under applicable statute only if a final, non-appealed determination on the claims at issue is found to demonstrate a high error rate. Such determination will only occur after THAH has exhausted all available Medicare administrative appeals for the disputed claims described herein. THAH contends that only 2 of the 100 sampled claims involved actual errors, an insufficient number of errors to justify extrapolation.

Extrapolation Inappropriate for Issues of Medical Necessity

THAH further believes extrapolation is particularly unwarranted since virtually all the claim denials relate to medical necessity issues. In potential False Claims Act liability situations, courts have found the following with respect to the application of extrapolation to medical necessity questions:¹⁰

Because "each and every claim at issue [is] "fact-dependent and wholly unrelated to each and every other claim, " and determining eligibility for "each of the patients involved a highly fact- intensive inquiry involving medical testimony after a thorough review of the detailed medical chart of each individual patient," . . . the case [is] not "suited for statistical sampling.'

Similarly, THAH contends that questions of medical necessity pertaining to a beneficiary's homebound status and need for skilled care also requires individualized determination. If necessary, THAH will appeal any use by CMS of extrapolation to determine estimated repayment liabilities based on claims denied for lack of medical necessity. THAH is confident its appeal of the claims at issue through Medicare's administrative appeals process will ultimately result in substantially favorable outcomes and a much lower payment error rate, if any.

Response to Audit Recommendations

⁸ Social Security Act, §1893(f)(3)

⁹ Medicare Program Integrity Manual (MPIM) Ch. 8 § 8.4.1.4

¹⁰ United States ex rel. Misty Wall v. Vista Hospice Care, Inc., 2016 WL 344983, at *12 (N.D. Tex. 2016)

HHS OIG recommends that Mercy Health VNS refund the extrapolated repayment amount of \$1,074,136 to its Medicare contractor. THAH agrees with HHS OIG's findings for the two claims previously discussed herein and has taken steps to refund \$2,028.83 in overpayments to its Medicare contractor. THAH disagrees with HHS OIG's audit findings for the remaining claims and intends to pursue all available Medicare administrative appeals with respect to such denials. Furthermore, THAH contends that extrapolation of an error rate is inappropriate for a low error rate and, in any event, is not appropriate until a final determination is made with respect to the appealed claims as explained previously.

HHS OIG also recommends Mercy Health VNS use reasonable diligence to identify and return any additional similar overpayments outside the HHS OIG audit period in accordance with the 60-Day Repayment Rule. The 60-Day Repayment Rule requires repayment of overpayments within 60 days of the overpayment being "identified." Guidance implementing the 60-Day Repayment Rule requires providers to conduct reasonable due diligence to confirm or contest an audit's findings.¹¹ THAH has conducted a thorough review of the medical records at issue and has determined, with exception of the two claims referenced previously, the services met all Medicare program requirements and were appropriately billed. Therefore, through its exercise of reasonable due diligence leading to the decision to appeal any denied claims, THAH believe it has fully complied with the 60-Day Rule.

HHS OIG further recommends Mercy VNS strengthen its controls to ensure full compliance with Medicare requirements pertaining to homebound status, and reasonable and necessary skilled care. THAH agrees there are always opportunities for improvement in internal controls. For this reason, THAH maintains a fully mature Integrity & Compliance Program that fully meets regulatory standards and guidelines. However, THAH contends no additional internal controls for Mercy VNS are needed based on its exercise of reasonable due diligence with respect to the audit findings and its response as described herein.

THAH appreciates the opportunity to provide its response to the Draft Audit Report. THAH takes its compliance efforts very seriously. We respectfully request HHS OIG reassess its initial findings contained in the Draft Audit Report in consideration of this response. We would welcome an opportunity for direct discussion with HHS OIG's medical reviewers concerning the audit findings.

Sincerely,

Mark McPherson
Interim President and Chief Executive Officer
Trinity Health at Home

¹¹ 81 Fed. Reg. 7654, 7667 (Feb. 12, 2016)